



ANDHRA PRADESH POLLUTION CONTROL BOARD
D.No. 33-26-14 D/2, Near Sunrise Hospital, Pushpa Hotel Centre,
Chalamalavari Street, Kasturibaipet, Vijayawada – 520010.

Website :www.pcb.ap.gov.in

CONSENT ORDER FOR ESTABLISHMENT

Order No.166 /APPCB/CFE/RO-VSP/HO/2013

Dt:15.06.2021

Sub: APPCB – CFE - **M/s. Eisai Pharmaceuticals India Pvt. Ltd, SEZ, Plot No.96, 97, 98, 124 & 126, JN Pharma City, Parawada, Visakhapatnam** – Consent for Establishment of the Board for **Change of Product Mix** under Sec. 25 of Water (P & C of P) Act, 1974 and Under Sec. 21 of Air (P & C of P) Act, 1981 - Issued - Reg.

Ref: 1) Industry's CFE(CPM) application received through A.P.OCMMS on 17.05.2021.
2) R.O's inspection report dt.27.05.2021.
3) CFE Committee meeting held on 03.06.2021.
4) RO mail dt.03.06.2021 regarding payment of balance fee by industry.

1. In the reference 1st cited, an application was submitted to the Board seeking Consent for Establishment (CFE) **Change of Product Mix** to produce the products with installed capacities as mentioned below, with an additional investment of Rs.0.01 Crore.

Existing as per CFE order dt.07.07.2020 :

S. No	Name of the Products and By-products	Quantity (TPM)	No. of Stages	Starting Raw Material	Quantity of Starting Raw Material (Kg/day)
Formulation (Million Units /Annum)					
1.	Aricept (Donepezil Hydrochloride)	60	---	---	---
2.	Myonal/EPRY (Eperisone Hydrochloride)	300	---	---	---
3.	DEC	400	---	---	---
4.	Pariet	500	---	---	---
5.	Warfarine	1200	---	---	---
6.	Urief Silodosin Packing only	20	---	---	---
7.	Methycobal	190	---	---	---
8.	Aricep 23 mg (Packing only)	15	---	---	---
9.	Teuri Packing only	20	---	---	---
10.	Merislon (Betahistine Mesilate) Tablets (Packing only)	20	---	---	---
11.	Zonegran (Zonisamide) Tablets (Packing only)	20	---	---	---
12.	Aricept M Forte	5	---	---	---

13.	Aricept M	5	---	---	---
14.	Alfence (Lorcaserin Tab 10 mg)	5	---	---	---
Total : 2760 Million Units /Annum					
Bulk Drugs (API) (Kg/day)					
15.	Donepezil Hydrochloride	5.55	3	5,6 Dimethyl Indanone	67
16.	Eperisone Hydrochloride	55.55	2	Ethyl Benzene	1100
17.	AKR (1-(3-chloro-5-(4- (4-chlorothiophen-2- yl)- cyclohexylpiperazin-1- yl)thiazol-2- ylcarbamoyl)piperidine- 4- carboxylic acid, monom aleate)	2.78	4	EPS130	45
18.	ESPA ((L-Lysine, compound with 4-[2- [(1R,2R)-2-(2,4- difluorophenyl)-1- methyl-2- [(phosphonoxy) methoxy]-3-(1H-1,2,4- triazol-1-yl)propyl]-4- thiazolyl]benzotrile and ethanol)	40.00	3	KSM	40
19.	Pranlukast Hydrate	132.00	2	4-Bromo methyl- 1,2- dihydro quinolone- 2-one	250
20.	Rebamipide	98.70	2	(E) -2 methyl-3- phenylacry ladehyde	60
21.	Epalrestat	13.70	2	N-(3. Acetyl-2- hydroxyph enyl)-4-(4- phenyl butoxy) benzamide	400
22.	EPS140	17.00	1	EPS130	45
23.	Azilsartan	9.00	3	Ethylchloro formate	58
24.	R&D and API Pilot plant products	20.00	--	—	—

25.	COVA	10.00	5	KSM-1	10.00
26.	SRCA	10.00	6	KSM-1	10.00
Total		414.28 Kg/day			

After Change of Product Mix:

S. No.	Name of the Products	Quantity	No. of Stages	Starting Raw Material	Quantity of Starting Raw Material (kg/day)
Formulation (Million units /annum)					
1.	Aricept (Donepezil Hydrochloride)	60	---	---	---
2.	Myonal/EPRY (Eperisone Hydrochloride)	300	---	---	---
3.	DEC	400	---	---	---
4.	Pariet	500	---	---	---
5.	Warfarine	1200	---	---	---
6.	Urief Silodosin Packing only	20	---	---	---
7.	Methycobal	190	---	---	---
8.	Aricep 23 mg (Packing only)	15	---	---	---
9.	Teuri Packing only	20	---	---	---
10.	Merislon (Betahistine Mesilate) Tablets (Packing only)	20	---	---	---
11.	Zonegran (Zonisamide) Tablets (Packing only)	20	---	---	---
12.	Aricept M Forte	5	---	---	---
13.	Aricept M	5	---	---	---
14.	Alfence (Lorcaserin Tab 10 mg)	5	---	---	---
Total		2760			
Bulk Drugs (API) (kg/day)					
15.	Donepezil Hydrochloride	2	3	5,6 Dimethyl Indanone	67
16.	Eperisone Hydrochloride	10	2	Ethyl Benzene	1100
17.	AKR (1-(3-chloro-5-(4-(4-chlorothiophen-2-yl)-cyclohexylpiperazin-1-yl)thiazol-2-ylcarbamoyl)piperidine-4-carboxylic acid, monomaleate)	2.78	4	EPS130	45

18.	ESPA ((L-Lysine, compound with 4-[2-[(1R,2R)-2-(2,4-difluorophenyl)-1-methyl-2-[(phosphonoxy)methoxy]-3-(1H-1,2,4-triazol-1-yl)propyl]-4-thiazolyl]benzotrile and ethanol)	40.00	3	KSM	40
19.	Pranlukast Hydrate	132.00	2	4-Bromo methyl-1,2-dihydro quinolone-2-one	250
20.	Rebamipide	44.60	2	(E) -2 methyl-3-phenylacryldehyde	60
21.	Epalrestat	13.70	2	N-(3-Acetyl-2-hydroxyphenyl)-4-(4-phenylbutoxy)benzamide	400
22.	EPS140	17.00	1	EPS130	45
23.	Azilsartan	9.00	3	Ethylchloroformate	58
24.	R & D and API Pilot plant products	20.00	--	—	—
25.	COVA	10.00	5	KSM-1	10.00
26.	SRCA	10.00	6	KSM-1	10.00
27.	AJM300	30.00	New		
28.	EZM030	5.00	New		
29.	HAND	15.00	New		
30.	RAM050	5.00	New		
31.	Edoxaban Tosylate	5.00	New		
	Total	371.08 kg/day			

- As per the application, the above activity is to be located within the existing industry premises located at **SEZ, Plot No.96, 97, 98,124 & 126, JN Pharma City, Parawada, Visakhapatnam** in an area of 50.67 acres.

3. The industry was inspected by the Asst. Environmental Engineer, Regional Office, Visakhapatnam, A.P Pollution Control Board on 20.05.2021 and observed that the site is surrounded by

North : Road followed by industrial plot of M/s.Ramky SEZ
South : SEZ Road
East : Granules Omnicem
West : SEZ Road

4. The Board, after careful scrutiny of the application and verification report of the Regional Officer, hereby issues **CONSENT FOR ESTABLISHMENT FOR CHANGE OF PRODUCT MIX** to the project under Section 25 of Water (Prevention & Control of Pollution) Act 1974 and Section 21 of Air (Prevention & Control of Pollution) Act, 1981 and the rules made there under. **This order is issued to manufacture the products as mentioned at para (1) only.**
5. This Consent Order now issued is subject to the conditions mentioned in the Annexure.
6. This order is issued from pollution control point of view only. Zoning and other regulations are not considered.
7. **This order is valid upto 7 years from the date of issue of the order**

Encl: Annexure.

JOINT CHIEF ENVIRONMENTAL ENGINEER UH-1 (FAC)

To

**M/s. Eisai Pharmaceuticals India Pvt. Ltd,
SEZ, Plot No.96, 97, 98, 124 & 126,
JN Pharma City, Parawada, Visakhapatnam
g-anand@eisai.co.in**

Copy to: 1. The JCEE, Z.O: Visakhapatnam for information and necessary action.
2. The E.E., R.O: Visakhapatnam for information and necessary action.

Annexure

1. The proponent shall obtain Consent for Operation (CFO) from APPCB, as required Under Sec.25/26 of the Water (P&C of P) Act, 1974 and under sec. 21/22 of the Air (P&C of P) Act, 1981, before commencement of the trail runs.
2. The applicant shall provide separate energy meters for Effluent Treatment Plant (ETP) and Air pollution Control equipments to record energy consumed. An alternative electric power source sufficient to operate all pollution control systems shall be provided.
3. The industry shall construct separate storm water drains. No effluents shall be discharged in to the storm water drains.

Water:

4. The source of water is JNPC and the maximum permitted water consumption is as following:

S. No.	Purpose	Quantity as per CFE order dt.07.07.2020 (KLD)	Quantity after CFE (CPM) (KLD)
1.	Process	25.2	25.2
2.	Washings Including floor & rector washings, QC, R&D water and scrubbing water	81.1	81.1
3.	Boiler , cooling tower and other utilities	322	322
4.	Fire Hydrant	1	1
5.	Gardening	190	190
6.	Domestic	70	70
	Total	689.3 KLD	689.3 KLD

Separate meters with necessary pipe-line shall be provided for assessing the quantity of water used for each of the purposes mentioned above.

5. The maximum waste water generation shall not exceed the following:

S. No	Source	Quantity as per CFE order dt.07.07.2020 (KLD)			Quantity after CFE (CPM) (KLD)		
		HTDS	LTDS	TOTAL	HTDS	LTDS	TOTAL
1	Process water	13.57	0	13.57	13.57	0	13.57
2	Process & Washings-Formulations	0	81.5	81.5	0	81.5	81.5
3	Boiler blow down	0	192	192	0	192	192
4	Cooling tower blow down						
5	DM Plant/Softner Regeneration water, EDI reject, Ro , ACF reject, MGF Reject water	0	63	63	0	63	63
6	Domestic effluent	0	63	63	0	63	63
	Total	13.57	336.5	350.07	13.57	336.5	350.07

Treatment & disposal:

Source	Treatment	Mode of final disposal
HTDS	Pretreatment (Neutralization)	To M/s. Ramky Pharmacy for further treatment
LTDS	Pretreatment (Neutralization)	To CETP of M/s. Ramky Pharmacy for further treatment and disposal
Domestic waste water	---	The overflow of the Septic tank shall be sent to the CETP for further treatment.

6. Effluents shall not be discharged on land or into any water bodies or aquifers under any circumstances.
7. The industry shall properly operate and maintain online real time monitoring system along with web camera facilities and shall ensure that it is connected to APPCB / CPCB websites as per CPCB directions.
8. Floor washing shall be admitted into the effluent collection system only and shall not be allowed to find their way in storm drains or open areas. All pipe valves, sewers, drains shall be leak proof.

Air:

9. The Air pollution Control equipment shall be maintained properly to comply with the following for controlling air pollution :

Existing as per CFE Order dt.07.07.2020:

S. No.	Details of Stack	Stack 1	Stack – 2, 3& 4
1	Attached to	Oil fired Boilers	D.G. Set
2	Capacity	2 X 3.0 TPH & 1 X 2.0 TPH	4 X 1500 KVA
3	Fuel	Oil	Diesel
4	Stack height	40 m common stack	8 m each
5	Control Equipment	--	Acoustic enclosures and silencers

After CPM: No changes in Air Emissions

10. A sampling port with removable dummy of not less than 15 cm diameter shall be provided in the stack at a distance of 8 times the diameter of the stack from the nearest constraint such as bends etc. A platform with suitable ladder shall be provided below 1 meter of sampling port to accommodate three persons with instruments. A 15 AMP 250 V plug point shall be provided on the platform.
11. The industry shall properly operate and maintain the monitoring system to all the stacks / vents in the plant. Regular monitoring shall be carried out and report shall be submitted to the Regional officer.

12. The industry shall properly operate and maintain multi-stage scrubbers to the process vents to control the process emissions. The industry shall ensure that online pH measuring facility with auto recording system is connected to the scrubbers.
13. The industry shall properly operate and maintain VOC monitoring system with auto recording facility.
14. The industry shall implement adequate measures to control all fugitive emissions from the plant.
15. The proponent shall ensure compliance of the National Ambient Air quality standards notified by MoEF, GoI vide notification No. GSR. 826 (E), dated. 16.11.2009 during construction and regular operational phase of the project at the periphery.

The generator shall be installed in a closed area with a silencer and suitable noise absorption systems. The ambient noise level shall not exceed 75 dB(A) during day time and 70 dB(A) during night time.

16. The proponent shall not use or generate odour causing substances or Mercaptans and cause odour nuisance in the surroundings.
17. The industry shall send the used / spent solvents to the recyclers (or) process them at their own solvent recovery facility within the premises.
18. The evaporation losses in solvents shall be controlled by taking the following measures:
 - i. Chilled brine circulation shall be carried out to effectively reduce the solvent losses into the atmosphere.
 - ii. Transfer of solvents shall be done by using pumps instead of manual handling.
 - iii. Closed centrifuges shall be used to reduce solvent losses.
 - iv. All the solvent storage tanks shall be connected with vent condensers to prevent solvent vapours.
 - v. The reactor vents shall be connected with primary & secondary condensers to prevent escaping of solvent vapour emissions into atmosphere.

Solid / Hazardous Waste:

19. The industry shall comply with the following for disposal of Solid waste:

S. No.	Name of the waste	Quantity as per CFE Order dt.07.07.2020	Quantity after CFE (CPM)	Mode of Disposal
1.	Used Oil / Waste Lubrication Oil	3000 LPA	3000 LPA	To authorized Re-processors / Recyclers / to the Cement industries for co-processing in the kiln.

2.	De- Toxified Containers & Liners	5 TPM	20TPM	To the authorized agencies/re-use/ recycle/TSDf, Parawada
3.	General waste (Like Thermo coal, Insulation waste, Contaminated Cotton waste, Centrifuge Bags, Used PPE's and other waste etc.,)	20 TPM	20TPM	Sent to authorized agencies/TSDf, Parawada
4.	Spent Catalyst	0.011 TPM	0.011 TPM	Recovery within the premises / to authorised agency for recovery / To M/s. Visakha Solvents, JNPC, Parawada
5.	Process Waste (including expired/defaced/rejected tablets, binder solutions, rejected or spilled APIs, Laboratory Wastes and utility wastes etc. and R&D Expired & rejected material)	16.38 TPM	16.38 TPM	To TSDf, Parawada for incineration (or) to the Cement industries/ AFRF.
6.	ETP Sludge	30 kg/day	30 kg/day	TSDf, Parawada for secured land filling.
7.	Spent Solvents	33.07 KLD	33.07 KLD	Recovery within the premises / to authorised agency for recovery / To M/s. Visakha Solvents, JNPC, Parawada
8.	E-waste	5TPM	5TPM	To Authorised collection centers
9.	Paper, cotton waste & packing materials i.e wood, carton & ropes etc.,	5TPM	5TPM	Sale to outside agencies/recyclers
10.	Metal scrap (MS,SS,GI & Aluminum)	50TPM	50TPM	
11.	Used Lead Acid Batteries	10 Nos. / annum	2 TPM9	To dealers on buy back system
12.	Glass Bottles / Scrap	3TPM	3TPM	To the authorized agencies/re-use/ recycle/TSDf, Parawada

20. The proponent shall place the chemical drums and / or any drums in a shed provided with concrete platform only. The Platform shall be provided with sufficient dyke wall and effluent collection system. The industry shall provide containers detoxification facility. Container & Container liners shall be detoxified at the specified covered platform with dyke walls and the wash wastewater shall be routed to low TDS collection tank.

21. The following rules and regulations notified by the MoEF&CC, Gol shall be implemented.

- a) Regulation of Persistent Organic Pollutants Rules, 2018.
- b) Hazardous waste and other wastes (Management and Transboundary Movement) Rules, 2016.
- c) Plastic Waste Management Rules, 2016.
- d) Manufacture, Storage and Import of Hazardous Chemicals Rules, 1989
- e) Fly Ash Notification, 2016.

- f) Batteries (Management & Handling) Rules, 2010.
- g) E-Waste (Management) Rules, 2016.
- h) Construction and Demolition waste Management Rules, 2016.
- i) Solid Waste Management Rules, 2016.
- j) The Public Liability Insurance Act, 1991 and its amendments thereof.

Other Conditions:

22. "The industry shall comply with the industry specific standards with respect to process emissions stipulated by the MoEF & CC, Gol, New Delhi from time to time."

S. No.	Details of process emissions	Emission Control system	Emission Standard
1	HCl	Multi stage water	35 mg/Nm ³
2	NH ₃	scrubbers and alkali	30 mg/Nm ³
3	Sulphuric acid mist	scrubbers	50 mg/Nm ³
4	Chlorine		15 mg/Nm ³

23. The industry shall display online data outside the main factory gate on quantity and nature of hazardous chemicals being used in the plant, water & air emissions and solid waste generated within the factory premises, as per Hon'ble Supreme Court order.
24. **The industry shall prepare a safety report and carry out an independent safety audit report of the respective industrial activities including chemical storages / isolated storages by an expert not associated with such industrial activity as required under Rule 10 of MSIHC Rules, 1989 and get it approved by the Factories Dept., and submit the compliance along with copy of the safety report, safety audit report and safety certificate at concerned Regional Office, APPCB.**
25. **The industry shall submit a copy of the NOC issued by the Andhra Pradesh State Disaster Response and Fire Service Dept., (APSDRFSD) at concerned Regional Office, APPCB.**
26. **The industry shall submit risk assessment report covering worst scenario clearly describing impact within the industry premises and outside the industry premises and emergency response system.**
27. The industry shall inventorize the storage quantities of hazardous chemicals (raw materials), products, as per the hazard nature of reactivity / toxicity / flammability / explosive stored/handling in the premises as defined in the Management of Storage, Import of Hazardous Chemicals (MSIHC) Rules, 1989 and the details shall be furnished to the Factories Department and to the Regional Office, APPCB on monthly basis duly certifying the same.
28. The industry shall identify major accident hazard chemicals & list out the hazardous chemicals endangered to human health & environment and the details shall be furnished to the Factories Department and to the Regional Office, APPCB time to time duly certifying the same by the industry. Further the industry shall extend training to the working personnels while handling hazardous chemicals for prevention of accidents and necessary antidotes to ensure the safety, as per the MSIHC Rules, 1989.

29. The industry shall carryout calibration of safety equipments and leak detection systems at regular intervals and shall certify the same with the Factories Department. That certified copy shall be submitted to the APPCB, Regional Office. The industry shall install fluorescent Wind Vane at the highest point in the industry premises.
30. **The industry shall comply with the Technical suggestions at Chapter No. 7.3 & 7.4 for Hazardous Chemical handling industries by High Power Committee (HPC) of Govt. of Andhra Pradesh. The HPC report is available at www.ap.gov.in.**
31. The industry shall utilize DG power for captive consumption only & power shall not be supplied to grid and shall follow the amendments issued by MoEF & CC/CPCB from time to time on DG sets in respect of conditions & standards.
32. Green belt shall be developed all along the boundary & vacant spaces with tall growing trees with good canopy and it shall not be less than 33% of the total area.
33. The industry shall submit the information regarding usage of Ozone Depleting Substance once in six months to the Regional Office and Zonal Office of the Board.
34. **The industry shall submit compliance to the conditions stipulated in the EC and CFE orders to the concerned Regional Officer of APPCB every six months and shall upload the same at APPCB website viz., [https://pcb.ap.gov.in/UI/Submission Compliance of EC CFE CFO Direction.aspx](https://pcb.ap.gov.in/UI/Submission%20Compliance%20of%20EC%20CFE%20CFO%20Direction.aspx).**
35. Concealing the factual data or submission of false information / fabricated data and failure to comply with any of the conditions mentioned in this order attracts action under the provisions of relevant pollution control Acts.
36. Notwithstanding anything contained in this conditional letter or consent, the Board hereby reserves its right and power Under Sec. 27(2) of Water (Prevention and Control of Pollution) Act, 1974 and Under Sec.21(4) of Air (Prevention and Control of Pollution) Act, 1981 to revoke the order, to review any or all the conditions imposed herein and to make such modifications as deemed fit and stipulate any additional conditions.
37. Any person aggrieved by an order made by the State Board under Section 25, Section 26, Section 27 of Water Act, 1974 or Section 21 of Air Act, 1981 may within thirty days from the date on which the order is communicated to him, prefer an appeal as per Andhra Pradesh Water Rules, 1976 and Air Rules,1982, to such authority (hereinafter referred to as the Appellate Authority) constituted under Section 28 of Water (Prevention and Control of Pollution)Act,1974 and Section 31 of the Air (Prevention and Control of Pollution) Act, 1981.

JOINT CHIEF ENVIRONMENTAL ENGINEER UH-1 (FAC)

To

**M/s. Eisai Pharmaceuticals India Pvt. Ltd,
SEZ, Plot No.96, 97, 98, 124 & 126,
JN Pharma City, Parawada, Visakhapatnam
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